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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GILLIGAN, CHRISTOPHER L	
ART UNIT	**PAPER NUMBER**
3626	

DATE MAILED: 09/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/900,278	ELETREBY ET AL.	
	Examiner	Art Unit	
	Luke Gilligan	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 25-53 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 25-53 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/10/01*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 25-53 have been examined.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 49-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 49 recites the limitation of "generating a report based on the querying step" where the report identifies "any" of each item listed in (a) through (h). It is unclear whether the report must include at least one piece of identifying information from items (a) though (h) or whether the report may include zero pieces of identifying information from any or all of items (a) through (h). For example, it is unclear whether the generated report must include at least one dosage irregularity (item (c)) or if the generated report may not include any dosage irregularities if not present for the patient. For Examination purposes, the Examiner will interpret the claim as generating a report that includes at least one of items (a) through (h).

4. Claims 50-53 contain the same deficiencies as claim 49 through dependency and, as such, are rejected for the same reasons.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

> granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims are rejected under 35 U.S.C. 102(e) as being anticipated by Mayaud, U.S. Patent No. 5,845,255.

7. As per claim 25, Mayaud teaches a method of managing pharmaceutical care of a patient comprising the steps of: providing drug data for a plurality of drugs in a clinical database, each drug having associated therewith a unique identifier comprising a first order representing a therapeutic class of the drug, a second order representing a therapeutic subclass of the drug, and a third order representing the drug (see column 37, lines 32-49); providing patient data for a plurality of patients in a patient database, the patient data comprising disease states and allergies for each respective patient (see column 19, lines 17-24); adding to the patient database data representing a therapy regimen of a patient, the therapy regimen comprising at least one prescribed drug, a frequency per day for each respective prescribed drug, a daily dosage for each respective prescribed drug, a date of last dispensing for each respective prescribed drug, a quantity of drug dispensed for each date of last dispensing for each respective prescribe drug, a quantity of drug remaining for each respective prescribed drug, and a compliance percentage (see column 28, lines 54-62); generating a plurality of progress reports for a patient, each progress report being generated at a different time (see column 21, lines 42-52); comparing a progress report with a plurality of monitoring parameters (see column 21, lines 53-55); and modifying the therapy regimen for a patient based upon the comparison of a progress report for the patient with the plurality of monitoring parameters (see column 21, lines 55-64).

8. As per claim 26, Mayaud teaches the method of claim 25 as described above. Mayaud further teaches comparing a first progress report with a second progress report, the first

progress report being generated earlier in time than the second progress report (see column 21, lines 53-55); and modifying the therapy regimen for the patient based upon the comparison of the first and second progress reports (see column 21, lines 55-64).

9. As per claim 27, Mayaud teaches the method of claim 25 as described above. Mayaud further teaches each unique identifier comprises a plurality of additional orders corresponding to additional information for the drug (see column 26, lines 39-45).

10. As per claim 28, Mayaud teaches the method of claim 25 as described above. Mayaud further teaches each unique identifier is linked to one or more disease states identified by an ICD9 (see Figure 7, in addition to linking drugs to disease states, it is well known in the art that these disease states have corresponding ICD9 identifiers).

11. As per claim 29, Mayaud teaches the method of claim 25 as described above. Mayaud further teaches documenting pharmacist interventions with me patient. wherein the pharmacist interventions comprise clinical interventions, patient-educational interventions, and patient compliance interventions (See column 15, lines 59-61, note that all transactions are documented).

12. As per claim 30, Mayaud teaches the method of claim 25 as described above. Mayaud further teaches constructing a therapy plan for the patient based upon an evaluation of the therapy regimen, the therapy plan comprising at least one medical problem, at least one medical- related goal, at least one course of therapy, and a plurality of monitoring parameters (see column 27, lines 7-12).

13. As per claim 32, Mayaud teaches the method of claim 25 as described above. Mayaud further teaches producing a printed report comprising information from the patient database (see column 39, lines 28-30).

14. Claims 33-36 recite substantially similar system limitations to those already addressed in method claims 25-28 and, as such, are rejected for similar reasons as given above.

15. As per claim 37, Mayaud teaches the system of claim 33 as described above. Mayaud further teaches each unique identifier comprises a plurality of characters, the plurality of characters having a first set of characters corresponding to the first order, a second set of characters corresponding to the second order. and a third set of characters corresponding to the third order (see Figure 8).

16. As per claim 38, Mayaud teaches the system of claim 37 as described above. Mayaud further teaches each unique identifier comprises at least eight characters (see Figure 8, note that, at least in some embodiments, a particular group of identifiers would comprise at least eight characters).

17. As per claim 39, Mayaud teaches the system of claim 33 as described above. Mayaud further teaches an integrated database, wherein the clinical database and patient database are maintained within the integrated database (see column 47, lines 29-46).

18. As per claim 40, Mayaud teaches the system of claim 33 as described above. Mayaud further teaches each therapeutic class of a drug identifies indications, contraindications, recommended dosages, adverse reactions, and drug-drug interactions for the drug (see column 14, lines 20-24).

19. As per claim 41, Mayaud teaches the system of claim 33 as described above. Mayaud further teaches each therapeutic class comprises therapeutically-related drugs usable for comparable indications (see Figure 8).

20. As per claim 42, Mayaud teaches the system of claim 33 as described above. Mayaud further teaches the therapy regimen data comprises a compliance percentage for a drug (see

column 28, lines 30-37, the Examiner notes that the recited formula equates to an amount of drug actually taken versus an amount prescribed which is what is reported on in Mayaud).

21. Claims 43-45 and 47 recite substantially similar limitations to those already addressed in claims 25, 33-34, 40, and 42 and, as such, are rejected for similar reasons as given above.

22. As per claim 46, Mayaud teaches the method of claim 44 as described above. Mayaud further teaches each therapeutic class comprises therapeutically-related drugs usable for comparable indications, and the method further comprises: comparing a prescribed drug in the therapy regimen with other prescribed drugs to identify prescribed drugs belonging to the same therapeutic class; and notifying a user if more than one prescribed drug in the same therapeutic class is present in the therapeutic regimen (see Figure 8, this display "notifies" the user by displaying the drugs in the same therapeutic class).

23. As per claim 48, Mayaud teaches the method of claim 43 as described above. Mayaud further teaches retrieving the indications and contraindications for a drug by reference to the unique identifier linked to that drug (see column 40, lines 20-37).

24. As per claim 49, Mayaud teaches a method of managing the pharmaceutical care of a patient using one or more software-accessible databases comprising the steps of: updating a patient database with a drug therapy regimen for the patient, the drug therapy regiment comprising an indication of each drug prescribed to the patient, a frequency per day for each drug, and a daily dosage for each drug (see column 26, lines 11-20); updating the patient database with patient data, the patient data comprising disease states and allergies for the patient (see column 19, lines 24-30); querying a clinical database with the drug therapy regimen and patient data (see column 31, lines 19-24); and generating a report based on the querying step, the report identifying at least one piece of information from the items listed in (a) through (h) (see column 19-63).

25. As per claim 50, Mayaud teaches the method of claim 49 as described above. Mayaud further teaches the report identifies the following additional information for each patient: (i) information regarding use or efficacy of any of the prescribed drugs (see column 32, lines 19-22); and (j) information regarding patient compliance (see column 28, lines 5-14).

26. As per claim 51, Mayaud teaches the method of claim 49 as described above. Mayaud further teaches the report identifies the following additional information for each patient: (k) information regarding an assessment of the educational needs of the patient (see column 30, lines 11-16, it is noted that some level of assessment of educational needs of the patient is required to determine who is a more needy patient requiring a dosing indicator device); and information regarding the financial circumstances of the patient (see column 15, lines 48-51, note that drug benefit status and insurance coverage are forms of financial circumstances).

27. As per claim 52, Mayaud teaches the method of claim 49 as described above. Mayaud further teaches the drug therapy regimen for the patient comprises a plurality of drugs prescribed by more than one physician (see column 25, lines 5-14).

28. As per claim 53, Mayaud teaches the method of claim 49 as described above. Mayaud further teaches modifying the drug therapy regimen based on the report (see column 32, lines 5-13).

Claim Rejections - 35 USC § 103

29. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

30. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mayaud, U.S. Patent No. 5,845,255 in view of Sillen et al., U.S. Patent No. 5,672,154.

31. As per claim 31, Mayaud teaches the method of claim 30 as described above. Mayaud does not explicitly teach the recited survey steps of claim 31. Sillen teaches a method for improving patient pharmaceutical care that includes the steps of analyzing a plurality fo surveys submitted by a patient, wherein each answer in a survey is assigned a numerical value, to derive a plurality of results for each survey (see column 3, lines 3-9 and liens 13-20); indexing each survey by date of completion (see column 3, liens 10-12); graphically displaying the results of the surveys, wherein the plurality of surveys is displayed simultaneously (see column 2, lines 58-65); and modifying the therapy plan based upon the results of the surveys (see column 3, line 65 – column 4, line 10). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the system of Mayaud. One of ordinary skill in the art would have been motivated to incorporate this feature for the purpose of improving the health states of patients with complicated diseases (see column 2, liens 22-26).

Conclusion

32. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Luke Gilligan whose telephone number is (571) 272-6770. The examiner can normally be reached on Monday-Friday 8am-5:30pm.

33. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

34. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

9/6/05

C. Luke Gilligan
Patent Examiner
Art Unit 3626